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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,393	01/31/2002	Francis Moussy	98-2163-P	3741
23413	7590	06/01/2007		
CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002			EXAMINER PREBILIC, PAUL B	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/066,393

Applicant(s)

MOUSSY ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 2-7, 12, 13, 15, 16, 20-29 and 31-37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 8-11, 14, 17-19, 30 and 38-66 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Supplemental Amendment

The supplemental reply filed on March 5, 2007 was not entered because supplemental replies are not entered as a matter of right except as provided in 37 CFR 1.111(a)(2)(ii). The amendment does not put the application in condition for allowance by being limited to an amendment that clearly advances prosecution; see 37 CFR 1.111 (2) (i), sections (A) to (F).

Election/Restrictions

Claims 2-7, 12, 13, 15, 16, 20-29, and 31-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper Numbers 11 and 15.

Claim Objections

Claims 11, 14, 17, 18, 41, 42, 46, 47, 52-54, 60, and 61 are objected to because of the following informalities:

With regard to claims 11, 49, 53, and 60, "nafion" is a registered trademark and the use thereof makes the claim scope unclear because it is a source of material not the material itself. It should be replaced with generic terminology of the same scope that is supported by the original specification.

With regard to claims 11, 14, 17, 18, 41, 46, 49, 52, 54, 60, and 61, the alternatives listing is not clearly limited to a closed group as required; see MPEP 2173.05(h). The language "combinations comprising at least one of the foregoing acids" appears to be open to any combination with the materials listed because of

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"comprising." The Examiner suggests replacing this language with "combinations of the foregoing acids" to overcome this objection.

With regard to claims 42 and 47, it is unclear how calling an "implant" a "device" further limits it since an implant is a type of device.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 9-11, 14, 17-19, 30, 38-49, 53, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Lerner et al (US 6,531,152). Lerner anticipates the claim language where the implant as claimed is the implantable device of Lerner, the crosslinked bioactive polymer as claimed is the coating of polyacid of polyacrylic acid; see column 15, line 47 et seq., and the microspheres as claimed are the microspheres of the core; see column 12, lines 3-7 and column 12, lines 55 et seq. Polyacrylic acid is one of the polyacids that the Applicants claim.

With regard to claims 9-11, the crosslinked acrylic acid polymer is a hydrogel in that it has the properties of one even if it is not called a hydrogel by name.

With regard to claims 17 to 19, Applicants are directed to column 17, line 15-62.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al (US 6,531,152) in view of Laub (US 5,945,446). Lerner discloses the use of various additives to the coating thereof but fails to disclose the use of humic acid. However, Laub teaches that it was known to use humic acid as an antiviral or antimicrobial additive; see column 1, lines 1-27. Therefore, it is the Examiner's position that it would have been obvious to use humic acid as an additive in the Lerner coating in order to give Lerner an antiviral and antimicrobial function as well as the functions provided by the other pharmaceutical additives.

Claims 57 and 64 are rejected under 35 U.S.C. 102(e) as anticipated by Lerner et al (US 6,531,152) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lerner et al (US 6,531,152) alone. Lerner discloses polymer microspheres but it is not clear that the peculiar product-by-process limitation "predegraded" is met; see MPEP 2113 that is incorporated herein by reference. The Examiner asserts that this limitation is met to the extent that the claimed process step would result in the same product as that disclosed by Lerner. It is noted that the degree of degradation is not specified.

Alternatively, the "predegraded" process step may result in a product that is slightly different from that of Lerner. Nonetheless, the Examiner asserts that the

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product implied by this process step would be so similar to the Lerner device that it would have been considered obvious to an ordinary artisan in the art.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al (US 6,531,152) in view of Zaffaroni (US 3,921,636). Lerner fails to disclose the use of one of the claimed materials in the bioactive polymer layer as claimed. However, Zaffaroni teaches that it was known to utilize one these materials, polyvinyl alcohol in a coating layer of similar devices; see column 7, lines 7-32. Therefore, it is the Examiner's position that it would have been obvious to utilize polyvinyl alcohol in the coating layer of Lerner for the same reasons that Zaffaroni utilizes the same.

Claims 52, 54-56, 58, 61-63, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al (US 6,531,152) in view of Boswell et al (US 3,773,919). Lerner fails to disclose utilizing the particular polymers of the microspheres as claimed. However, Boswell teaches that it was known to utilize polylactides (i.e. polylactic acid), polyglycolides (i.e. polyglycolic acid), and copolymers of these materials in similar devices; see the abstract and column 7, line 12 et seq. Therefore, it is the Examiner's position that it would have been obvious to utilize these materials in the microspheres of Lerner for the same reasons that Boswell utilizes the same.

Claims 59 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al (US 6,531,152) in view of Hubbell et al (US 5,801,033). Lerner fails to disclose the utilization of PEG (polyethylene glycol) in the microspheres thereof. However, Hubbell teaches that it was known to utilize PEG in similar devices; see the abstract and column 11, line 16 et seq. Therefore, it is the Examiner's position that it

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would have been obvious to utilize PEG in the microspheres of Lerner for the same reasons that Hubbell utilizes the same.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

With regard to the argument that a polyacid is limited to only those materials that have multiple acid groups; see page 13, line 1 of the response filed February 5, 2007. However, polyacrylic acids (i.e. polyacrylates) are clearly within the scope of this term because the same materials are disclosed and claimed as being examples of polyacids. Moreover, the prior art also understands the term in this way; see US 4,014,987 on column 1, line 60 to column 2, line 6 and US 4,036,227 on column 17, lines 1-29. Moreover, humic acid is a material of undefined vegetable decay acids so it is not clear that contains molecules with more than one acid group. For these reasons, the Examiner has interpreted "polyacid" as encompassing polyacrylic acid.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Paul Prebilic
Primary Examiner
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